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10/538,918	12/13/2005	John E. Hansen	13323-105003	5673
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KING & SPALDING 1185 AVENUE OF THE AMERICAS NEW YORK, NY 10036-4003				
EXAMINER				
HAND, MELANIE JO				
ART UNIT		PAPER NUMBER		
3761				
NOTIFICATION DATE		DELIVERY MODE		
05/14/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomailnyc@kslaw.com

### Office Action Summary

**Application No.**

10/538,918

**Applicant(s)**

HANSEN ET AL.

**Examiner**

MELANIE J. HAND

**Art Unit**

3761

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1.88, 91-95, 97-106, 118-120, 130-136, 138-141, 143-158 and 160-164 is/are pending in the application.
- 4a) Of the above claim(s) 95, 130-136, 141, 143, 144 and 146-158 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1.88, 91-94, 96-106, 118-120, 138-140, 142, 145 and 160-164 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 2/6/09
- 4) ☐ Interview Summary (PTO-813)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 6, 2009 has been entered.

### ***Response to Arguments***

2. Applicant's arguments with respect to claims 1 and 91 have been considered but are moot in view of the new ground(s) of rejection.

3. Applicant's remarks regarding the personal interview conducted on January 28, 2009 regarding the improper election by original presentation are acknowledged. As agreed, claims 91-106, 118-120 and 137-164 are examined on the merits in this action. However it is noted that the amendment to claim 95 to recite the step of swiping a dry second swab rather than swiping the pre-wetted area of step I with a swab (which could be dry or not) renders claim 95 directed to a method that is materially different from those which have been examined on the merits.

### ***Election/Restrictions***

4. Amended claims 95, 141, 144 and 146-158 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: with respect to independent claims 95 and 141, the claims now recite a wet-sampling and dry sampling step or simply a step of swiping a pre-wetted surface with a second dry swab.

Previously, the claims did not recite the step of a second swab swiping the pre-wetted are that was specifically wet or dry. This amendment to the claims renders the methods recited in claims 95 and 141 materially different from that which was previously claimed and examined on the merits. Claims 144 and 146-158 depend directly or ultimately from claim 141. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 95 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

#### ***Information Disclosure Statement***

5. The information disclosure statement (IDS) submitted on February 6, 2009 was filed after the mailing date of the final action on August 7, 2008. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

#### ***Claim Objections***

6. Claim 95 is objected to because of the following informalities: it is suggested that the phrase "followed by" be placed with step i) of the recited method to prevent potential objection or rejection for lack of antecedent basis. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 91-94, 97-99, 101, 103, 105, 106, 118-120, 138-140, 161, 163 and 164 are rejected under 35 U.S.C. 102(b) as being anticipated by Kelly (see PTO-892 for full citation).

With respect to **claim 91**: Kelly discloses a kit comprising the following: i) a swab and a handle attached to said swab, wherein said swab is a gelatin-based sponge, i.e. a Gelfoam swab; and ii) an agent in the form of Stuart Transport Medium, which is considered herein to be a neutral diluent inasmuch as its final pH is  $7.4 \pm 0.2$  (see attached reference material for Stuart Transport Medium).

With respect to **claim 92**: The neutral diluent disclosed by Kelly is Stuart Transport Medium, which is an organic buffer.

With respect to **claim 93**: Kelly discloses a method for collecting a target from a collection medium, namely a wound environment, comprising the following steps: i) providing a Gelfoam swab, i.e. a swab comprising gelatin; and ii) making contact between the swab and the target, i.e. bacteria in the wound, to transfer said target from the collection medium to the swab; and iii) transferring said target from the swab to a transfer medium, i.e. Stuart's transport medium, to thereby recover said target from said collection medium.

With respect to **claim 94**: The swab comprises a gelatin-based sponge inasmuch as it comprises a Gelfoam swab, which is by its nature a gelatin-based sponge.

With respect to **claim 97**: Kelly discloses a method of lowering the amount of a target, i.e. bacteria, in a sample area, i.e. a wound comprising the following steps: (i) making contact between a Gelfoam swab comprising gelatin and at least a portion of said sample area, so that an amount of the target adheres to the swab, defining the bacteriological swabs disclosed by Kelly, and (ii) transferring the adhered target from the swab to a transfer medium, namely Stuart transport medium.

With respect to **claim 98**: The collection medium is a wound surface, i.e. combination of a solid surface, a semi-solid surface, and a liquid.

With respect to **claim 99**: The target disclosed by Kelly is a microorganism, i.e. bacteria.

With respect to **claim 101**: Kelly discloses the transfer of bacteria onto the swab, wherein bacteria exhibit enzymatic activity in a wound environment and on the swab, producing enzymes that digest gelatin. Thus, it is examiner's position that the transferring step inherently and necessarily includes digestion of said gelatin.

With respect to **claim 103**: The digestion inherently and necessarily disclosed by Kelly comprises addition of an agent, namely enzyme produced by the bacteria.

With respect to **claim 105**: The method of Kelly further comprises the step of contacting said swab with an agent, namely Stuart Transport medium, considered herein to be a neutral diluent inasmuch as its final pH is  $7.4 \pm 0.2$  (see attached reference material for Stuart Transport Medium).

With respect to **claim 106**: The method disclosed by Kelly further comprises culturing cells collected on the swab in a growth medium inasmuch as Kelly discloses an operative swab culture, wherein a culture by its nature requires a growth medium to perform its intended function.

With respect to **claim 118**: The micro-organism disclosed by Kelly is bacteria.

With respect to **claim 119**: The mammalian cell disclosed by Kelly and picked up by the swab is a cell from blood plasma, inasmuch as the surface that is swiped by the swab is a wound surface containing blood.

With respect to **claim 120**: The mammalian cell disclosed by Kelly is any of leukocytes, erythrocytes and thrombocytes since the swab picks up whole blood from the wound surface.

With respect to **claims 138**: The swab comprising gelatin disclosed by Kelly is attached to a support, namely a handle.

With respect to **claim 139**: The support disclosed by Kelly comprises wood.

With respect to **claim 140**: The support disclosed by Kelly is a handle.

With respect to **claim 161**: Kelly discloses the transfer of bacteria onto the swab, wherein bacteria exhibit enzymatic activity that digests gelatin. Thus it is examiner's position that the transferring step includes digestion of said gelatin.

With respect to **claim 163**: The method of Kelly further comprises the step of contacting said swab with an agent, namely Stuart Transport medium, considered herein to be a neutral diluent inasmuch as its final pH is  $7.4 \pm 0.2$  (see attached reference material for Stuart Transport Medium).

With respect to **claim 164**: The method disclosed by Kelly further comprises culturing cells collected on the swab in a growth medium inasmuch as Kelly discloses an operative swab culture, wherein a culture by its nature requires a growth medium to perform its intended function.

***Claim Rejections - 35 USC § 103***

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).



11. Claims 1 and 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelly in view of D'Alessio et al (U.S. Patent No. 6,283,933).

With respect to **claim 1**: Kelly discloses a single-use device for sampling or collecting comprising a sterile swab and a handle attached to said swab in the form of a wooden-handled Gelfoam® swab, wherein said swab is a gelatin-based sponge inasmuch as any swab containing Gelfoam, which is made from gelatin (see attached Gelfoam product sheet), is gelatin-based. Kelly does not explicitly disclose that the device is contained in a sealed package. However, handled swabs contained in sealed packaged to keep them sterile prior to use are well known in the art as supported by D'Alessio et al (Col. 6, line 66 – Col. 7, line 8) and prevent contamination as well as premature evaporation of any alcohol impregnated in the swab. Therefore, it would be obvious to one of ordinary skill in the art to modify the device of Kelly so as to be contained in a sealed package as disclosed by D'Alessio with a reasonable expectation of success to ensure sterility of the swab prior to use.

With respect to **claim 88**: The gelatin-based sponge disclosed by Kelly has a water absorption capacity of up to 45 g/g (see attached sheet), which overlaps the claimed range of at least 30 g/g. With regard to the limitation "as determined by USP method "Absorbable Gelatin Sponge: Water Absorption", The test method recited in the claim *per se* does not substantially affect the value of a specific parameter, which is a characteristic of the material and depends on the structure and make up of a material, but not on the method of its determination. Since the test method does not essentially affect the composition of the Gelfoam material in the swab during testing, the test method bears little patentable weight because any test method will yield

substantially identical results, and thus the test method used cannot be the basis for patentability over the prior art.

12. Claims 100 and 160 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelly in view of Lea et al (U.S. Patent Application Publication No. 2002/0019062)

With respect to **claim 100**: Kelly does not disclose that the target is an organic molecule. However, the use of swabs to swipe surfaces for organic molecules such as proteins are well known in the art as supported by Lea et al ('062, ¶¶0014,0117) Therefore, it would be obvious to one of ordinary skill in the art to modify the method of Kelly such that the target is a protein as disclosed by Lea with a reasonable expectation of success to provide a means for diagnostic testing of said protein.

With respect to **claim 160**: Kelly does not explicitly disclose a pre-wetted swab. However, collecting samples with pre-wetted swabs is well-known in the art as supported by Lea (U.S. Patent Application Publication No. 2002/0019062, ¶0117) as swabs are often wetted with a buffer solution or other collection enhancing composition to ease the collection and separation of sample cells from the swab for transport and diagnostics. Therefore it would be obvious to one of ordinary skill in the art to modify the method of Kelly such that the swab is pre-wetted as disclosed by Lea with a reasonable expectation of success to facilitate acquisition of target material from the wound.

13. Claims 102 and 162 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelly in view of Laskey et al (U.S. Patent No. 6,303,323).

With respect to **claim 102**: Kelly does not explicitly disclose that the transferring step includes the washing of said target from the swab. Laskey disclose a method of antigen retrieval from a sample, wherein, in the process of transferring the sample for antibody staining, a washing buffer is used. Laskey discloses that the antigen retrieval process is known in the art. Since the method of Laskey seeks to solve a similar problem in the art to that with which applicant is concerned, it would be obvious to one of ordinary skill in the art to modify the method of Kelly such that the transferring step includes washing of the target from the swab with a reasonable expectation of success to ensure all of the target material is available for testing and diagnosis.

With respect to **claim 162**: Kelly does not explicitly disclose that the transferring step includes the washing of said target from the swab. Laskey disclose a method of antigen retrieval from a sample, wherein, in the process of transferring the sample for antibody staining, a washing buffer is used. Laskey discloses that the antigen retrieval process is known in the art. Since the method of Laskey seeks to solve a similar problem in the art to that with which applicant is concerned, it would be obvious to one of ordinary skill in the art to modify the method of Kelly such that the transferring step includes washing of the target from the swab with a reasonable expectation of success to ensure all of the target material is available for testing and diagnosis.

14. Claim 104 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kelly in view of Ranjane et al (JP 09-296004 A (Derwent Abstract only)).

With respect to **claim 104**: Kelly does not disclose that the method further comprises extraction of the target by membrane filtration. Ranjane discloses extraction of bacterial cells from a sample via membrane filtration. Since the method of Ranjane seeks to solve a similar problem

in the art to that with which applicant is concerned and discloses extraction of the bacteria for further investigation and synthesis, it would be obvious to one of ordinary skill in the art to modify the method of Kelly such that the method further comprises the step of extraction of the target by membrane filtration to allow portions of the target to be set aside for further analysis and/or synthesis.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/

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